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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,527	07/01/2003	David Griggs	01189/2	5315
28997	7590	05/19/2006	EXAMINER	
HARNES, DICKEY, & PIERCE, P.L.C 7700 BONHOMME, STE 400 ST. LOUIS, MO 63105			HADDAD, MAHER M	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/611,527

Applicant(s)

GRIGGS ET AL.

Examiner

Maher M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

### DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-4, 27, and 38, drawn to ESM-1 polypeptides, a composition thereof, fragments thereof, and a chimeric molecule comprising said polypeptides; classified in Class 530, subclasses 395, 837, and 866.
- II. Claims 5-14, drawn to an isolated nucleic acid molecules encoding ESM-1 polypeptides; vectors, host cells, and methods of producing the polypeptide and a microarray, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- III. Claims 15-21 and 28-29, drawn to an antibody that immunospecifically-binds to ESM-1 polypeptide, a composition and a kit; classified in Class 530, subclass 387.3, and 391.1; Class 424, subclass 133.1; Class 435, subclass 810.
- IV. Claim 22, drawn to a method of identifying an agent that binds to ESM-1 polypeptide, classified in Class 435, subclass 7.1.
- V. Claim 23, drawn to a method of identifying an agent that modulates the expression or activity of ESM-1 polypeptide, classified in Class 435, subclass 7.1.
- VI. Claim 24, drawn to a method for modulating the activity of the ESM-1 polypeptide comprising contacting a cell sample expressing the ESM-1 polypeptide with a compound, classified in Class 435, subclass 7.21.
- VII. Claim 25, drawn to a method of treating or preventing an angiogenesis associated disorder comprising administering ESM-1 polypeptide, classified in Class 514, subclass 2.
- VIII. Claim 26, drawn to a method of treating or preventing an angiogenesis associated disorder comprising administering an antibody to EMS-1 polypeptide, classified in Class 424, subclass 145.1.
- IX. Claims 30-31, drawn to a method for detecting differentially expressed genes correlated with a cancerous state of a mammalian cell with probe, classified in Class 435, subclass 6.
- X. Claim 32, drawn to a method for monitoring the progression of an angiogenic disorder in a patient by detecting the expression of ESM-1 polypeptide, classified in Class 424, subclass 9.1.

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- XI. Claim 33, drawn to a method of assessing the efficacy of a test compound for inhibiting angiogenesis by detecting expression of ESM-1 polypeptide in a sample, classified in Class 435, subclass 7.1.
- XII. Claim 34, drawn to a method of assessing the efficacy of a therapy for inhibiting angiogenesis by detecting expression of ESM-1 polypeptide in a sample, classified in Class 424, subclass 9.2.
- XIII. Claim 35, drawn to a method of selecting a composition for inhibiting angiogenesis in a patient by exposing aliquots of a sample in the presence of a plurality of test compositions, classified in Class 424, subclass 7.1.
- XIV. Claims 36-37, drawn to an ESM-1 polypeptide antagonist wherein said antagonist is an antisense molecule, classified in Class 536, subclass 23.1.
- XV. Claims 39-40, drawn to a transgenic non-human mammal having integrated into its genome a nucleic acid sequence encoding ESM-1 operatively linked to regulatory elements, classified in Class 800, subclass 18.
- XVI. Claim 41, drawn to a transgenic knockout non-human mammal comprising a homozygous disruption in its endogenous ESM-1 gene, classified in Class 800, subclass 8.

2. Groups I-III and XIV-XVI are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides, antisense, transgenic animals differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups IV-XIII are different methods. A method of identifying, a method of modulating, a method detecting, a method for monitoring, a method of assessing, a method of selecting and a method of treating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups I/ VII and III/VIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used for affinity purification, in addition to the methods of treating recited. In the instant case the polypeptide of Group I can be used for affinity purification, in addition to the methods of treating recited.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods

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of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

### *Species Election*

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

- A. If any one Group I-XVI is elected, applicant is required to elect a particular ESM-1 polypeptide such as a) SEQ ID NO: 2, b) SEQ ID NO: 19 or c) SEQ ID NO: 3. These are distinct species because their structures and physiochemical properties and modes of action are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter**

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of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 5, 2006

*Maher Haddad*  
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